



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1904]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Comparing Food Safety Knowledge, Attitude and Behavior Among English-dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title “Comparing Food Safety Knowledge, Attitude and Behavior Among English-dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002,

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Comparing Food Safety Knowledge, Attitude and Behavior Among English-dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers--

OMB Control Number 0910-NEW

I. Background

We conduct research and educational and public information programs relating to food safety and nutrition issued in our broad statutory authority, set forth in section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)), to protect the public health by ensuring that foods are “safe, wholesome, sanitary, and properly labeled,” and in section 1003(d)(2)(C) of the FD&C Act (21 U.S.C. 393(d)(2)(C)), to conduct research relating to foods, drugs, cosmetics, devices and tobacco products.

Our current food safety education and outreach programs and materials generally are developed and provided for the English-speaking population in the United States (U.S.) (Ref. 1). To better protect public health and to help consumers practice safe food handling, we need empirical data on how different population groups understand, perceive and practice food safety and food handling. An emerging and important demographic trend in the United States is the increase in Hispanics. Recent estimates suggest that Hispanics (defined as those who identify themselves as of Hispanic or Latino origin) are the largest and fastest growing minority group in the nation; the proportion of the U.S. population that was Hispanic was 14 percent in 2005 and is projected to increase to 29 percent in 2050 (Ref. 2).

Data from the Centers for Disease Control and Prevention (CDC) indicate that, in the past two decades, Hispanics were one of the population groups that often experienced higher incidence rates (per 100,000 population) of bacterial causes of foodborne illness than Caucasians (Ref. 3). These bacterial causes include Campylobacter, Listeria monocytogenes (Listeria), Shigella, and Salmonella. While some Hispanics living in the United States use the English language exclusively or more often than Spanish (English-dominant Hispanics), other U.S. Hispanics predominantly use the Spanish language in their daily lives (Spanish-dominant Hispanics) (Ref. 4). Since most U.S. food labels, including safe food handling instructions, are in English, Spanish-dominant Hispanics' understanding and use of safe food handling instructions may differ from that of English-dominant Hispanics and of non-Hispanics who use English exclusively. In addition, Hispanics may have certain food handling practices that may increase their risk of foodborne illness (Ref. 5).

FDA needs an understanding of how different population groups perceive and behave in terms of food safety and food handling to inform development of possible measures that we may take to better protect public health and to help consumers practice safe food handling. FDA is aware of no consumer research on a nationwide level on how different population groups understand, perceive and practice food safety and food handling. This study is intended to provide initial answers to research questions such as whether and how much Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics differ in their knowledge, attitude, and behavior toward food safety and food handling and the role that demographic and other factors may play in any differences.

The proposed study will use a Web-based instrument to collect information from 3,000 adult members in online consumer panels maintained by a contractor. The study plans to

randomly select 1,000 panel members in each of three groups: Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics. Both English and Spanish questionnaires will be used, as appropriate. The study plans to include topics such as: (1) Food safety knowledge and attitude; and (2) food handling and consumption practice. To help us understand the data, the study will also collect information on respondents' background, including, but not limited to, health status and demographic characteristics, such as age, gender, education, and income, and degree of acculturation among Hispanic respondents using a measure developed by Marin et al. (Ref. 6).

The study is part of our continuing effort to protect the public health. We will not use the results of the study to develop population estimates. We plan to use the results of the study to develop follow-up quantitative and qualitative research to gauge the prevalence and extent of differences in food safety knowledge and behaviors between the three mentioned population groups. We plan to use the results of the follow-up research to help inform the design of effective education and outreach initiatives aimed at helping reduce the risk of foodborne illness for the general U.S. population as well as Hispanics.

In the Federal Register of November 28, 2014 (79 FR 70875), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview screener	72	1	72	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1.5 (90 minutes)	14
Pretest invitation	1,440	1	1,440	0.033 (2 minutes)	48
Pretest	180	1	180	0.25 (15 minutes)	45
Study invitation	24,000	1	24,000	0.033 (2 minutes)	792
Study	3,000	1	3,000	0.25 (15 minutes)	750
Total					1,655

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on prior experience with research that is similar to this proposed study. We will use a cognitive interview screener with 72 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 5.976 hours, rounded to 6 hours. We will conduct cognitive interviews with nine participants. We estimate that it will take a participant approximately 90 minutes to complete the interview, for a total of 13.5 hours, rounded to 14 hours. We also plan to conduct a pretest to identify and resolve potential survey administration problems. We will send a pretest invitation to 1,440 prospective pretest participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 47.52 hours, rounded to 48 hours. We will administer the pretest with 180 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 45 hours. We will send a study invitation to 24,000 prospective participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 792 hours. We will administer the study with 3,000 participants and estimate that it will take a participant 15 minutes (0.25 hours)

to complete the study, for a total of 750 hours. The total estimated burden for all the study activities is 1,655 hours; this estimate is 9 hours higher than that shown in the 60-day notice due to revised hours for cognitive interviews, from 30 minutes (0.5 hours) to 90 minutes (1.5 hours) each interview.

II. References

1. U.S. Food and Drug Administration. "Foodborne Illness & Contaminants." June 9, 2014. (<http://www.fda.gov/Food/FoodborneIllnessContaminants/default.htm>).
2. Passel, J.S. and C. D’Vera. "U.S. Population Projections: 2005-2050." Pew Research Center. February 11, 2008. (<http://pewhispanic.org/files/reports/85.pdf>).
3. Quinlan, J.J. "Foodborne Illness Incidence Rates and Food Safety Risks for Populations of Low Socioeconomic Status and Minority Race/Ethnicity: A Review of the Literature." International Journal of Environmental Research and Public Health 10(8): 3634-3652, 2013.
4. Taylor, P., M.H. Lopez, J. Martínez and G.Velasco. "Language Use Among Latinos." Pew Research Center. April 4, 2012. (<http://www.pewhispanic.org/2012/04/04/iv-language-use-among-latinos/>).
5. Henley, S.C., S.E. Stein and J.J. Quinlan. "Identification of Unique Food Handling Practices That Could Represent Food Safety Risks for Minority Consumers." Journal of Food Protection 75: 2050-2054, 2012.
6. Marin, G., F. Sabogal, B.V. Marin, et al. "Development of a Short Acculturation Scale for Hispanics." Hispanic Journal of Behavioral Sciences 9(2): 183-205, 1987.

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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